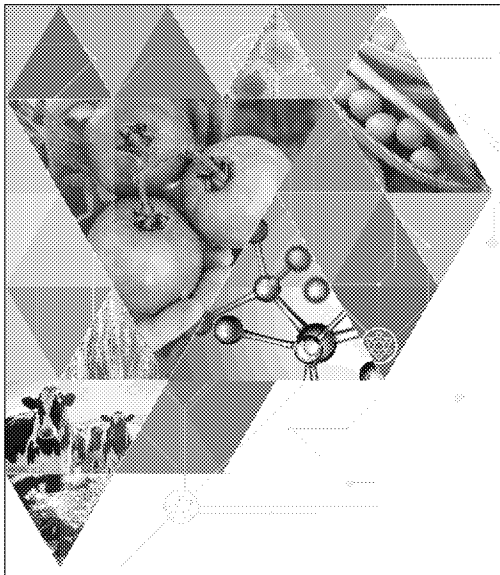

23 October 2019

Risk assessment of combined exposure to multiple chemicals in EFSA

Ongoing and future activities

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Trusted science for safe food

efsa
European Food Safety Authority

Background

2007 — 2009 — 2011 — 2013 — 2015 — 2017 — 2019

Regulation 396/2005
Setting of MRLs for pesticides

Regulation 1107/2009
Placing on the market of PPPs

"..take into account known cumulative and synergistic effects of pesticides when the methods are available.."

Development activities for pesticides

- *Tiered methodology for cumulative risk assessment (PPR, 2009)*
- *Methodology for probabilistic exposure assessment (PPR, 2012)*
- *Methodology for cumulative assessment groups (PPR, 2013)*
- *Monte Carlo Risk Assessment software (ACROPOLIS Project, 2013)*

Pilot assessment for pesticides

- *Effects on the thyroid and the nervous system*
- *Framework partnership agreement with RIVM (MCRA software)*
- *Issued for public consultation in 2019*

Cross-cutting activities

- *Scientific colloquium (2015)*
- *Guidance on risk assessment of combined exposure to multiple chemicals (SC, 2019)*

Pilot Pesticides – Scope

- **Retrospective risk assessment:**
  - Official pesticide monitoring data (Art.32 Reg. 396/2005)
  - Reference period 2014-2016
- **Target organs:**
  - Thyroid (chronic)
  - Nervous system (acute)
- **Population groups:**
  - Adults (BE, CZ, DE, IT)
  - Children (BG, FR, NL)
  - Toddlers (DK, NL, UK)
- **Food commodities:**
  - 30 Raw primary commodities (plant origin only, most frequently consumed)
  - Food for infants and young children
  - Water

Pilot Pesticides – Conclusions

- **Threshold for regulatory consideration**

- **Overall conclusion**

  Taking account of the available data and the uncertainties involved, it is concluded that cumulative exposure to pesticides that have acute effects on the nervous system or chronic effects on the thyroid does not exceed the threshold for regulatory consideration established by risk managers.

- **Factors driving the acute exposure distributions**
  - Single substances in a specific commodity (75% of the upper part)
  - Commodities exceeding the MRL (40 to 95%)

Pilot Pesticides - What about the US?

EU

- ***Regulation (EC) No 1107/2009:*** "ensure that the chances of failing to detect adverse effects or of under-estimating their importance are reduced to a minimum"
- Grouping based on the similarity of ***mode of action*** or ***phenomenological effects***
- Cumulative effects of N-methyl carbamates and organophosphorus assessed ***jointly*** for AChE inhibition

US

- ***Food Quality Protection Act:*** "cumulative effects of such [pesticide] residues and other substances that have a common mechanism of toxicity."
- Grouping based on the similarity of ***mode of action***
- Cumulative effects of N-methyl carbamates and organophosphates assessed ***separately*** for AChE inhibition

▶ **Difference is in the problem formulation**

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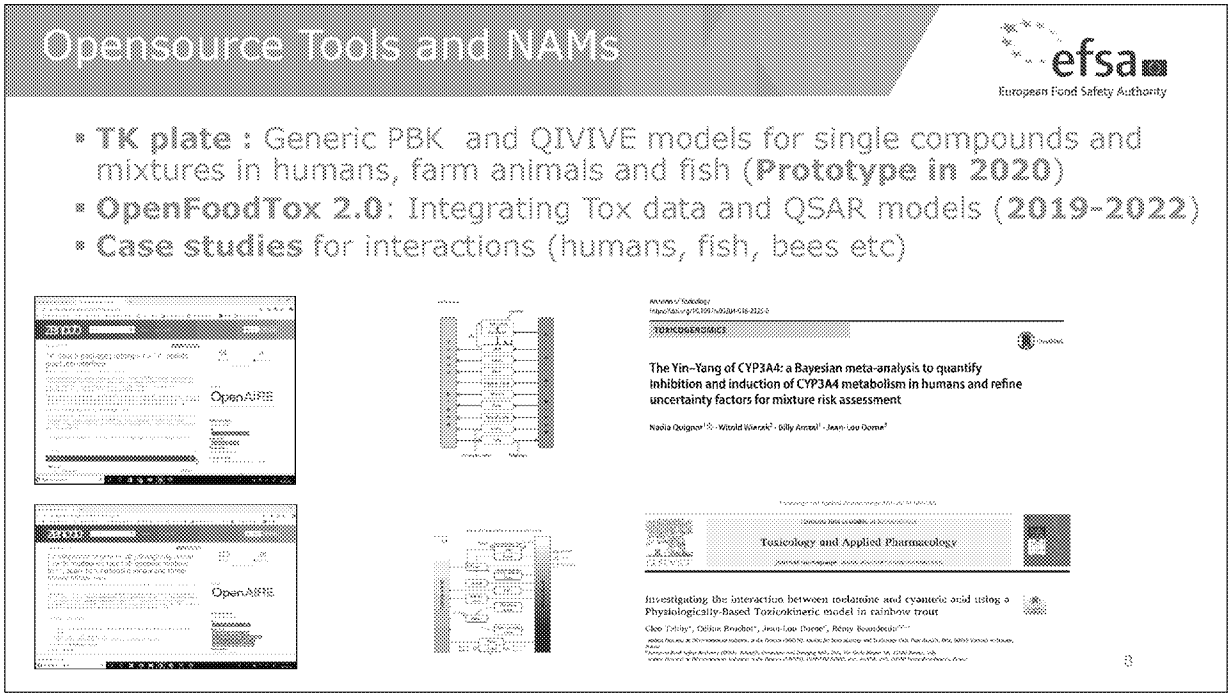
Pilot assessment is under public consultation

- Launched on 17 September 2019
- Stakeholder event on 22 October 2019
- Deadline for commenting ***15 November 2019***
- Final assessment by 31 March 202

Don't miss the opportunity to have your say!!!

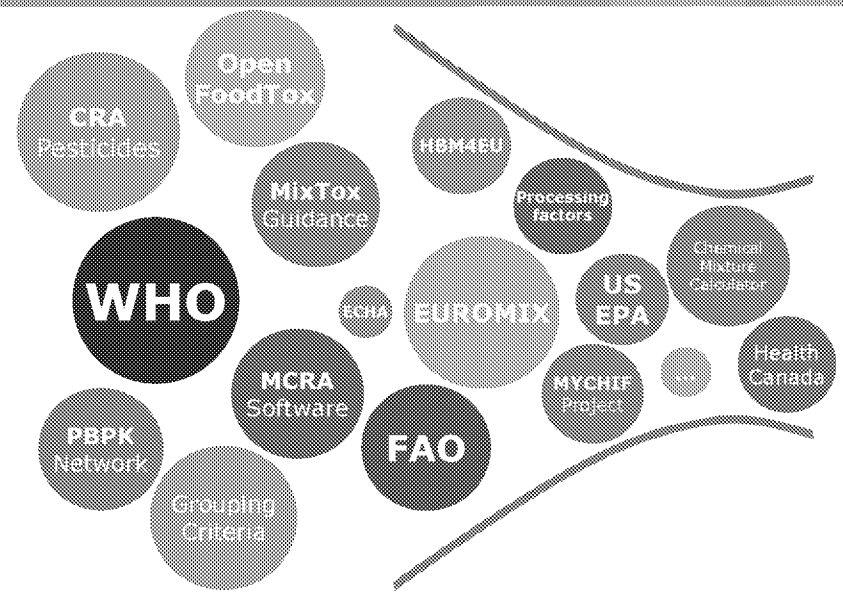
Scientific Opinion On Criteria for grouping chemicals into Assessment groups

- **Scientific principles** MIXTOX GD + **other relevant** cross-cutting GD (**WoE, biological relevance, uncertainty**).
- **RA** (**prioritisation, urgent RA, pre- and post-market RA**), data availability, time and resources (**problem formulation**).
- **Tiering principles** + **range fit for purpose scenarios** consider available hazard/ exposure info as well as AOP, TK and HBM
- **Relevant EFSA areas** (CAG, CONTAM), EU +**international activities**. Consistency and harmonisation, avoid duplication.
- **End of 2020** for public consultation and published in the spring 2021.



EFSA is building Tkplate for modelling kinetics in humans, farm animals and the env. Prototypes and models are available and a first version will be released in 2020 with several models.

Cooperation activities – EU Roadmap



EU Roadmap

Combined Exposure to Multiple Chemicals

- EFSA Advisory Forum
- EFSA MixTox Workshop
- International Liaison Group for methods on Risk Assessment of Chemicals in Food (ILMERAC)
- Group on Accelerating the Pace for Chemical Risk Assessment (APCRA)

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